

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

THIS DOCUMENT RELATES TO:

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) MDL No. 1456
) Civil Action No. 01-12257-PBS

) Judge Patti B. Saris

)
) The City of New York v. Abbott Labs., et al.
) (S.D.N.Y. No. 04-CV-06054)
) County of Suffolk v. Abbott Labs., et al.
) (E.D.N.Y. No. CV-03-229)
) County of Westchester v. Abbott Labs., et al.
) (S.D.N.Y. No. 03-CV-6178)
) County of Rockland v. Abbott Labs., et al.
) (S.D.N.Y. No. 03-CV-7055)
) County of Dutchess v. Abbott Labs, et al.
) (S.D.N.Y. No. 05-CV-06458)
) County of Putnam v. Abbott Labs, et al.
) (S.D.N.Y. No. 05-CV-04740)
) County of Washington v. Abbott Labs, et al.
) (N.D.N.Y. No. 05-CV-00408)
) County of Rensselaer v. Abbott Labs, et al.
) (N.D.N.Y. No. 05-CV-00422)
) County of Albany v. Abbott Labs, et al.
) (N.D.N.Y. No. 05-CV-00425)
) County of Warren v. Abbott Labs, et al.
) (N.D.N.Y. No. 05-CV-00468)
) County of Greene v. Abbott Labs, et al.
) (N.D.N.Y. No. 05-CV-00474)
) County of Saratoga v. Abbott Labs, et al.
) (N.D.N.Y. No. 05-CV-00478)
) County of Columbia v. Abbott Labs, et al.
) (N.D.N.Y. No. 05-CV-00867)
) Essex County v. Abbott Labs, et al.
) (N.D.N.Y. No. 05-CV-00878)
) County of Chenango v. Abbott Labs, et al.
) (N.D.N.Y. No. 05-CV-00354)
) County of Broome v. Abbott Labs, et al.
) (N.D.N.Y. No. 05-CV-00456)
) County of Onondaga v. Abbott Labs, et al.
) (N.D.N.Y. No. 05-CV-00088)
)

County of Tompkins v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00397))
County of Cayuga v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00423))
County of Madison v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00714))
County of Cortland v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00881))
County of Herkimer v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00415))
County of Oneida v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00489))
County of Fulton v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00519))
County of St. Lawrence v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00479))
County of Jefferson v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00715))
County of Lewis v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00839))
County of Chautauqua v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06204))
County of Allegany v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06231))
County of Cattaraugus v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06242))
County of Genesee v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06206))
County of Wayne v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06138))
County of Monroe v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06148))
County of Yates v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06172))
County of Niagara v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06296))
County of Seneca v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06370))
County of Orleans v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06371))
County of Ontario v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06373))
County of Schuyler v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06387))
County of Steuben v. Abbott Labs, et al.)

(W.D.N.Y. No. 05-CV-06223))
County of Chemung v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06744))
County of Ulster v. Abbott Labs, et al.)
(N.D.N.Y. Case No. 06-CV-0123))
County of Wyoming v. Abbott Labs, et al.)
(W.D.N.Y. Case No. 05-CV-6379))
)
AND)
)
County of Nassau v. Abbott Labs, et al.)
(E.D.N.Y. No. 04-CV-5126))
)

**DEFENDANT ASTRAZENECA’S INDIVIDUAL REPLY
MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANTS’
JOINT MOTION TO DISMISS**

Defendant AstraZeneca Pharmaceuticals LP (“AstraZeneca”) respectfully submits this individual reply memorandum in further support of its motion to dismiss the Consolidated Complaint¹ and the Second Amended Complaint of Nassau County (the “Nassau Complaint” and, together with the Consolidated Complaint, the “Complaints”) as they relate to AstraZeneca’s drug Zoladex.

ARGUMENT

In their Opposition to AstraZeneca’s Individual Motion to Dismiss (the “Opposition”), Plaintiffs concede that their claims regarding Zoladex for the period January 1991 through December 3, 2003 have been previously settled and released according to the terms of the Settlement Agreement between AstraZeneca and the New York (attached as Exhibit A to AstraZeneca’s

¹ Terms not defined herein have the meaning attributed to them in the Joint Defendants Memorandum of Law in Support of Motion to Dismiss.

Individual Motion to Dismiss). Nonetheless, Plaintiffs argues that its Zoladex claims for the time from December 3, 2003 to the present are still viable because the settlement bars claims only through the agreement's effective date.

However, since June 2003, New York State (the entity that sets the Medicaid reimbursement levels that the counties and City of New York are required to pay) has had at its disposal not only the AWP's published for Zoladex but the very pricing information Plaintiffs claim should have been disclosed. As is described in the Complaints, AstraZeneca entered into a Corporate Integrity Agreement with the Office of Inspector General of the US Department of Health and Human Services (the "CIA") on June 4, 2003.² *See* Cons. Comp. at ¶¶ 265-269; Nassau Comp. at ¶¶ 253-257. Pursuant to the terms of the CIA, AstraZeneca reports the "Average Sale Price"³ for Zoladex and certain other specified drugs to,

² This agreement has been posted by the U.S. Department of Health and Human Services, and is publicly available on its website. *See* <http://oig.hhs.gov/fraud/cia/agreements/AstraZeneca06042003.PDF>. A copy of the CIA is also attached as Exhibit A to the accompanying declaration of Lucy Fowler, Esq.

³ Section III.D. of the CIA defines the term "Average Sale Price" as follows:

with respect to each dosage, form, strength and volume of [Zoladex and certain other specified drugs]... the average of all final sales prices charged by AstraZeneca for the product in the United States to all purchasers, excluding those sales exempt from inclusion in the calculation of 'Best Price' for Medicaid Drug Rebate purposes, pursuant to 42 U.S.C. § 1396r-8, and excluding identifiable direct sales to hospitals. (Those purchasers for which the sales are included in the calculation of Average Sale Price are hereafter referred to as the 'Relevant Purchasers'.) The prices identified in the calculation of the Average Sale Price should be net of all the following: volume discounts; prompt pay discounts; cash discounts; chargebacks; short-dated product discounts; free goods; rebates [footnote omitted]; and all other price concessions provided by AstraZeneca to any Relevant Purchaser that result in a reduction of the ultimate cost to the purchaser....

among others, New York State, the Office of the Inspector General, CMS and First DataBank. *See* CIA § III.D.2.b.

In their Complaints, Plaintiffs argue that New York State, and therefore the plaintiff counties and City of New York, has been overcharged for its Medicaid payments because these payments have been made based on AWP's that, Plaintiffs allege, were "false and inflated." *See, e.g.*, Cons. Comp. at ¶ 8; Nassau Comp. at ¶ 6. According to the Consolidated Complaint, "Reliance on AWP is a virtual necessity given that defendants conceal their more accurate pricing information, contending it is proprietary." Cons. Comp. at ¶ 10; *see also* Nassau Comp. at ¶ 5, 29 ("States rely on AWP in part because defendants intentionally and fraudulently conceal their true prices."), 77 ("Actual transaction price data – the amounts actually paid by providers for drugs – is not readily publicly available.... This makes it practically impossible to efficiently and accurately calculate Medicaid reimbursements based on anything other than AWP.").

On their face, these allegations fail to state a claim with respect to Zoladex in the time following the Settlement Agreement, for one simple reason: no matter what AWP may be, since June 2003, it has *not* been the only pricing information available for Zoladex. Rather, since that time – a full six months prior to execution of the Settlement Agreement – AstraZeneca has provided to the State of New York ASPs that by their definition include the "actual transaction price data" without which Plaintiffs claim to have been defrauded. Moreover, the Complaints contain no allegations or even suggestions (and nor could they) that AstraZeneca has failed to comply with the terms of this agreement. Thus, Plaintiffs'

Complaints fail to state a claim upon which relief can be granted with respect to Zoladex in the post-settlement period (December 3, 2003 to the present).

In sum, all of Plaintiffs' claims against AstraZeneca relating to Zoladex should be dismissed.

Dated: Boston, Massachusetts
May 11, 2006

Respectfully submitted,

By: /s/ Lucy Fowler
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Inc., and AstraZeneca LP*

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on May 11, 2006, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Lucy Fowler
Lucy Fowler